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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/849,657 | 05/04/2001 | Harry M. Meade | G0744.70005US00 | 9001 |

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GTC BIOTHERAPEUTICS, INC.,
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| EXAMINER |
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HAMA, JOANNE

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| ART UNIT | PAPER NUMBER |
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1632

| SHORTENED STATUTORY PERIOD OF RESPONSE | MAIL DATE | DELIVERY MODE |
|--|------------|---------------|
| 3 MONTHS | 04/09/2007 | PAPER |

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

09/849,657

Applicant(s)

MEADE ET AL.

Examiner

Joanne Hama, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 December 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 10, 14-16, 18, 19 and 25 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 10, 14-16, 18, 19 and 25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicant filed a response to the Office Action of June 29, 2006 on December 26, 2006. Claims 1-9, 11-13, 17, 20-24 are cancelled. Claims 10, 14, 15, 18, 19, 25 are amended.

Claims 10, 14-16, 18, 19, 25 are under consideration.

Information Disclosure Statement

Applicant filed an Information Disclosure Statement (IDS) on December 26, 2006. The IDS has been considered.

Withdrawn Rejections

35 U.S.C. § 112, 1st parag., New Matter

Applicant's arguments, see page 4 of Applicant's response, filed December 26, 2006, with respect to the rejection of claim 26 have been fully considered and are persuasive. Applicant has cancelled claim 26. The rejection of claim 26 has been withdrawn.

35 U.S.C. § 112, 1st parag. Enablement

Applicant's arguments, see pages 4-5 of Applicant's response, filed December 26, 2006, with respect to the rejection of claims 10, 14-17, 19, 26 have been fully considered and are persuasive. Applicant indicates that the claims are amended and are directed to methods for producing or obtaining decorin in the milk of a non-human

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mammal as well as to non-human mammals that produce decorin in their milk. The rejection of claims 10, 14-16, 19 has been withdrawn. It is noted that the rejection of claims 17, 26 is withdrawn as the claims are cancelled.

35 U.S.C. § 102(b)

Applicant's arguments, see page 5 of Applicant's response, filed December 26, 2006, with respect to the rejection of claim 19 have been fully considered and are persuasive. Applicant indicates that claim 19 has been amended and is directed to a transgenic non-human mammal. The rejection of claim 19 has been withdrawn.

New/Maintained Rejections

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 18 is newly rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. Amended claim 18 is drawn to a method. However, it is unclear what the method is for or what the method accomplishes.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 10, 14-16, 18, 19, 25 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Houdebine et al., U.S. Patent 5,965,788, patented October 12, 1999, previously presented, in view of Isaka et al., 1996, Nature Medicine, 2: 418-423, see IDS, and Roberts et al., 1992, Gene, 121: 255-262, previously presented, for reasons of record, June 29, 2006.

Applicant's arguments filed December 26, 2006 have been fully considered but they are not persuasive.

Applicant indicates that the Examiner has not sufficiently demonstrated that the successful production of decorin in the milk of a non-human mammal as claimed would have been reasonably expected at the time of filing. Applicant indicates that the teachings presented by the Examiner in regard to the ability to express decorin are the teachings of Isaka which demonstrate that its expression was difficult and that the Examiner has not demonstrated why at the time of filing decorin would have been expected to be expressed at high levels in light of Isaka if *arguendo* the teachings of the references could be combined to obtain the methods and non-human mammal of the rejected claims. Applicant indicates that the Examiner has improperly used hindsight to arrive at the conclusion of a reasonable expectation of success with the references cited. With regard to the issue that the Examiner has used improper hindsight reasoning, according to the MPEP 2145, Consideration of Applicant's Rebuttal Arguments, X). A). Impermissible Hindsight, "[a]ny judgement on obviousness is in a

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sense necessarily a reconstruction based on hindsight reasoning, but so long as it takes into account only knowledge which was within the level of ordinary skill in the art at the time the claimed invention was made and does not include knowledge gleaned only from applicant's disclosure, such a reconstruction is proper." In re McLaughlin 443 F.2d 1392, 1395, 170 USPQ 209, 212 (CCPA 1971), the Examiner has not used improper hindsight because the Examiner relied upon Houdebine for teaching that transgenic non-human mammals can be used as bioreactors, wherein a protein of interest is secreted into the milk. Houdebine teaches that large amounts of the protein of interest are produced when using these transgenic non-human mammals. As for the specific embodiments of a goat beta-casein promoter taught by Roberts et al., the promoter controls expression of the most abundant protein in goat milk. With regard to Isaka et al., decorin has therapeutic value and that there is a need in the art for decorin protein to be made in large quantities such that it can be used in therapeutic applications. Further, Isaka et al. teach that there is difficulty in obtaining large amounts of decorin and the methods as claimed do not recite any level of expression. Houdebine provides the expectation that any difficulties experienced by Isaka et al. in their system would be overcome by using the transgenic bioreactor. Thus, these publications provide motivation for an artisan to use these particular elements in the bioreactor model taught by Houdebine. There would have been reasonable expectation of success that human decorin could be expressed in milk of the transgenic non-human mammal that expressed it because Houdebine teaches that transgenic non-human mammal used as a bioreactor is a good way of obtaining large amounts of a protein of interest.

Thus, the rejection is maintained.

It is noted that the rejection of claim 17 is withdrawn as the claim has been cancelled.

Conclusion

No claims allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joanne Hama, Ph.D. whose telephone number is 571-272-2911. The examiner can normally be reached Monday through Thursday and alternate Fridays from 9:00-5:00.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras, can be reached on 571-272-4517. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public. For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

JH

ANNE M. WEHBE' PH.D
PRIMARY EXAMINER

